Reply and Amendment U.S. Serial No. 09/019,441

Attorney Reference: <u>037003-0275470</u>

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## **REMARKS**

Entry of the foregoing amendments, reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow are respectfully requested.

With respect to the present amendments, applicants advise at the outset that they maintain all the arguments set forth in Applicants previous Replies. However, in the interest of expediting prosecution, Applicants have presented a new set of claims all of which correspond to chimeric anti-human CD23 antibodies containing variable region sequences contained in the exemplified anti-human CD23 antibodies.

In particular, claims 42-47 correspond to chimeric anti-human CD23 antibodies wherein the heavy and light variable region is that of the 6G5 antibody (see pages 44-47 of specification) and claims 48-59 correspond to chimeric anti-CD23 antibodies comprising the variable heavy and light chains of 5E8 (see page 50-54 of application) exactly or 5E8 modified at position 75 in the heavy chain to incorporate a lysine residue (see page 59).

Additionally, both sets of claims provide that the chimeric antibody contains a human gamma –1 or gamma –3 constant region.

It is anticipated that claims should be free of the outstanding prior art rejections because quite clearly none of the cited references teach or suggest chimeric anti-human CD23 antibodies containing these specific sequences.

Applicants respectfully advise that they intend to pursue claims of the original scope in a continuation application, and are merely submitting these claims to expedite allowance of the present claims as they correspond to Applicants preferred commercial embodiments.

Indeed, Applicants maintain for the reasons of record that the cited references do not fairly teach or suggest that the subject chimeric anti-CD23 antibodies which contain human gamma –1 or gamma –3 constant domains, especially in view of the state of the art as evidenced by previous literature which suggested that Fc effector functions were <u>not</u> necessary for the induction of IgE inhibition by anti-human CD23 antibodies.

As discussed at page 17 of the application, it was surprisingly found by the present inventor that gamma –4 versions derived from the exemplified antibodies exhibit significantly better IgE inhibitory activity than antibodies containing different or no constant regions. This enhancement therefor is an unexpected result and is believed to provide compelling evidence as to why the previous prior art rejections should not be maintained.

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In any event, the subject claims should be allowable absent any reference teaching or suggesting antibodies containing the variable heavy and light chain sequence recited in the present claims.

Based on the foregoing, this application is believed to be in condition for allowance.

A Notice to that effect is respectfully solicited.

Respectfully submitted,

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Attachment: Clean Copy of Claims

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## **CLEAN COPY OF CLAIMS**

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## IN THE CLAIMS

- 42. A chimeric anti-human CD23 antibody which the variable light domain comprises the polypeptide encoded by SEQ ID NO: 1, the variable heavy domain comprises the polypeptide encoded by SEQ ID NO: 2, and comprising a human constant region selected from the group consisting of human gamma –1 and human gamma –3 constant regions.
- 43. The anti-human CD23 antibody of claim 42 wherein the human constant region is a human gamma –1 constant region.
- 44. The anti-human CD23 antibody of claim 42 wherein the human constant region is a human gamma –3 constant region.
- 45. A pharmaceutical composition containing an anti-human CD23 antibody according to claim 42 and a pharmaceutically acceptable carrier.
- 46. A pharmaceutical composition containing an anti-human CD23 antibody according to claim 43 and a pharmaceutically acceptable carrier.
- 47. A pharmaceutical composition containing an anti-human CD23 antibody according to claim 44 and a pharmaceutically acceptable carrier.
- 48. A chimeric anti-human CD23 antibody wherein the variable light domain comprises the polypeptide encoded by SEQ ID NO: 3 and the variable may domain comprises the polypeptide encoded by SEQ ID NO: 4 and a human constant region selected from the group consisting of a human gamma –1 constant region and a human gamma –3 constant region.
- 49. A chimeric anti-human CD23 antibody wherein the variable light domain comprises the polypeptide encoded by SEQ ID NO: 3 and the variable heavy domain comprises the polypeptide encoded by SEQ ID NO: 4 with the exception that the asparagine colon at position 75 is replaced with a lysine.
- 50. The anti-human CD23 antibody according to claim 48 which comprises a human gamma –1 constant region.
- 51. The anti-human CD23 antibody according to claim 48 which comprises a human gamma –3 constant region.

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- 52. The anti-human CD23 antibody according to claim 49 which comprises gamma –1 constant region.
- 53. The anti-human CD23 antibody according to claim 49 which comprises a human gamma –3 constant region.
- 54. A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 48 and a pharmaceutically acceptable carrier.
- 55. A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 49 and a pharmaceutically acceptable carrier.
- 56. A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 50 and a pharmaceutically acceptable carrier.
- A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 51 and a pharmaceutically acceptable carrier.
- 58. A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 52 and a pharmaceutically acceptable carrier.
- 59. A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 53 and a pharmaceutically acceptable carrier.
- 60. A pharmaceutical composition comprising an anti-human CD23 antibody according to claim 54 and a pharmaceutically acceptable carrier.